

## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>5</sup> :

A61B 17/32

A1

(11) International Publication Number:

WO 93/1664

(43) International Publication Date:

2 September 1993 (02.09.93)

(21) International Application Number: PCT/US93/01264

(22) International Filing Date: 12 February 1993 (12.02.93)

(30) Priority data:

07/840,372

24 February 1992 (24.02.92) US

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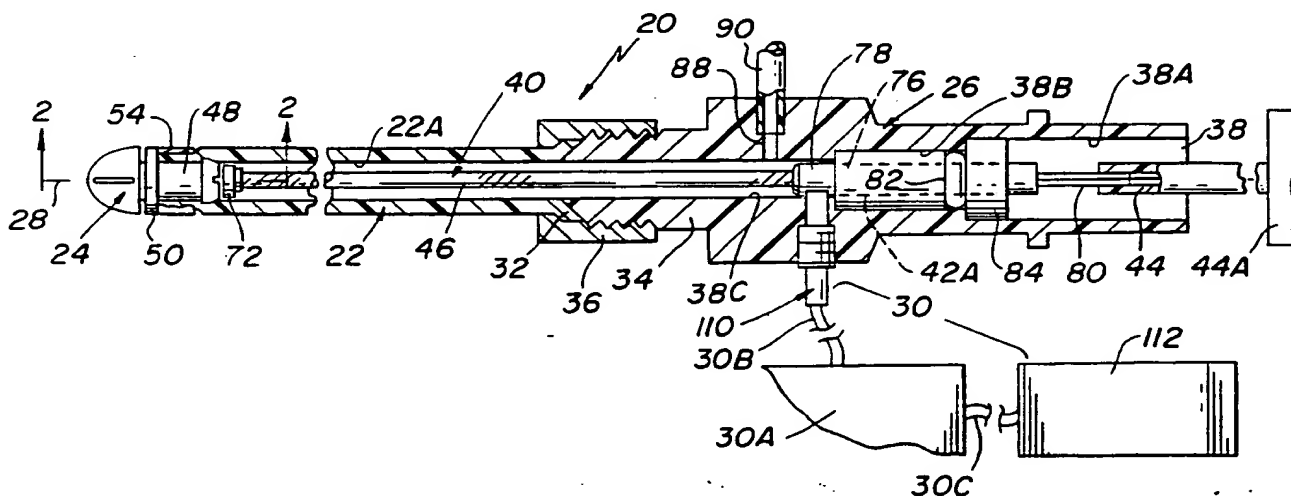
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(81) Designated States: AU, BB, BG, BR, CA, CZ, FI, HU, JP, KP, KR, LK, MG, MN, MW, NO, PL, RO, RU, SE, SK, UA, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, SN, TD, TG).

## Published

*With international search report.**Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.*

(54) Title: ELECTROSURGICAL CATHETER INSTRUMENT WITH IMPACTING WORKING HEAD



## (57) Abstract

Apparatus (20) and a method for cauterizing and/or removing or debulking tissue located on the surface or within the body of a living being. The apparatus (20) comprises a catheter having a distal end portion at which a working head (24) is located. The working head (24) is arranged to be moved, e.g., rotated, repeated by a drive system (40) including an electrically conductive cable (46). The cable (46) is connected between the working head (24) and one electrode of an electrosurgical power supply (30). The other electrode of the supply is connected to a plate arranged to engage a portion of the being's skin. The working head (24) is arranged to be located adjacent the biological material and to be rotated at a relatively high speed to sweep a localized intense electrical current (e.g., arc) across a portion of tissue located immediately adjacent the working head (24). The repeated movement of the working head impacts the tissue to debulk it.

ELECTROSURGICAL CATHETER INSTRUMENT WITH  
IMPACTING WORKING HEAD

Field of the Invention

This invention relates generally to medical devices and procedures, more particularly to apparatus and methods for applying an electrical energy to biological material on or within the body of a living being to effect the burning or cauterization of such material alone or in combination with the debulking or removal thereof.

Background of the Invention

The prior art includes various diathermic devices for burning, cutting, and cauterizing tissue within the body of a patient. One such device is commonly referred to as an electrosurgical instrument. That instrument typically includes one electrode, in the form of a small operating tip which is connected to one, e.g., the positive, terminal of an electrosurge generator, e.g., a high frequency electrical source. The tip is arranged to be brought into engagement or very close proximity to the tissue to be treated so that an intense (dense) electric current or arc is produced between the instrument's tip and the tissue. In order to complete the electrical circuit, the other, e.g., negative, terminal of the generator is normally connected to a rather large plate electrode (typically grounded) in electrical contact with the skin of the patient. As discussed in United States Patent No. 4,034,761 (Prater et al.), the electrical signals provided by the generator may be of different characters to effect a different procedure. Thus, the signals may be of the type referred to as "cutting signals" for effecting the cutting of tissue by destroying (e.g., burning) the tissue cells adjacent the electrode tip. The signals may also be of the type referred to as "coagulation or hemostasis signals" for dehydrating or shrinking of blood vessel walls around a contained clot of coagulated blood, thereby fusing the vessel to seal off the flow of blood. The generator may produce a blend of the cutting and coagulating signals, such combined signals

It is still a further object of this invention to provide an electrosurgical apparatus which is of wide utility.

#### Summary of the Invention

These and other objects of the instant invention are achieved by providing apparatus and methods for effecting some medical procedure on biological material or tissue located on the exterior surface or within the body of a living being.

The apparatus comprises an instrument, e.g., a catheter, having a distal end portion at which a working head is located, drive means, and power means. The working head is arranged to be located, e.g., introduced percutaneously or through a natural orifice, immediately adjacent the biological material (e.g., tissue) to be treated and once so located is repeatedly moved, e.g., rotated, at a relatively high speed with respect thereto. The power means is arranged to provide electrosurgical current to the working head, whereupon an intense localized flow of electrical current (e.g., an arc) is swept across a portion of the biological material.

In accordance with one preferred embodiment of this invention the working head includes surface portions arranged to repeatedly impact the biological material, e.g., highly vascular tissue, to debulk it while the arc cauterizes it.

#### Description of the Drawings

Other objects and many of the attendant advantages of this invention will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawing wherein:

Fig. 1 is a side elevational view, partially in section, of an electrosurgical apparatus constructed in accordance with this invention;

Fig. 2 is an enlarged sectional view taken along lines 2 - 2 of Fig. 1 and showing one embodiment of a working head of the subject apparatus;

In any case the working head is arranged to be brought into engagement or very close proximity to the biological material to be treated and then repeatedly moved or scanned thereacross. In the exemplary embodiments of the working heads shown and described herein, each includes a pair of impacting surfaces (to be described later), which when the working head is rotated, repeatedly impact the biological material (e.g., tissue) to be treated, to emulsify it into small pieces or particles, thereby debulking it.

The instrument 20 includes electrosurgical means 30 for effecting cauterization or hemostasis of internally located tissue. This feature is of considerable importance, particularly in applications wherein the material being impacted or debulked is highly vascular tissue, e.g., the prostate, liver and kidney.

As can be seen clearly in Fig. 1, the jacket portion 22 of the catheter comprises a thin walled tube formed of any suitable material having good electrical insulating properties, e.g., plastic, and has a small outside diameter. In the preferred embodiment herein, the outside diameter is approximately 2.25 mm (8 French). This size is merely exemplary. Thus, the jacket 22 may be either smaller or larger, depending upon the application to which the catheter 20 will be put.

The proximal end of the jacket 22 is in the form of a flared flange 32 which is arranged to be connected to the proximal end 34 of the catheter's body portion 26 via a threaded cap 36. The body portion 26 is a generally hollow, electrically insulating, member including a central passageway 38 extending therethrough. It is within this passageway that the drive assembly 40 for the catheter is located. The passageway 38 includes three sections, 38A, 38B and 38C, each of different internal diameter. The distal-most section 38C has an internal diameter which is the same as the hollow passageway 22A extending through the catheter jacket 22. In fact, passageway section 38C is essentially coaxial with the hollow interior 22A of the jacket 22. The

distilled non-conducting water) which is used to lubricate the drive assembly 40 flows (as will be described later). In order to enable that liquid to flow through the bushing each groove includes an axial groove or inlet slot 58 at its proximal end. The distal end of each groove 56 is open at the free end of the catheter.

In accordance with the preferred embodiment of this invention, the bushing 48 is formed of an electrically insulating material, e.g., Torlon (a polyetherimide).

Any type of working head can be utilized in the catheter 20. In the embodiment shown herein, the working head 24 is constructed generally in accordance with the teachings of United States Letters Patent No. 4,747,821, entitled "Catheter With High Speed Moving Working Head", which is assigned to the same assignee as this invention and whose disclosure is incorporated by reference herein. However, the working head 24 of this invention includes electrically insulating and electrically conductive portions, not disclosed in that patent in order to form a portion of the electrosurge means 30.

The details of one embodiment of the working head 24 will now be described with reference to Figs. 1, 2 and 7. As can be seen therein, that working head basically comprises a convex crown 62 and a mounting shank 64. The working head is mounted in the catheter's distal end so that its shank, which projects proximally from its crown, passes into the bore 52 in the bushing 48 at the distal end of the catheter. The crown 62 includes a pair of non-sharp impacting surfaces 66A and 66B. These surfaces are arranged to repeatedly impact the biological material, e.g., tissue, to be treated when the working head is rotated (or oscillated) about longitudinal axis 28 to pulverize or emulsify that material into very small-sized particles as described in the heretofore identified U.S. Patent No. 4,747,821. The impacting surfaces 66A and 66B are formed by rounded or radius edges at the interface of the outer convex surface of the working head's crown and a respective pair of relieved, e.g., flatted,

portion 80 of square outer periphery. The proximal portion 80 of the coupling is arranged to be disposed within a correspondingly shaped bore 44A in the output drive shaft 44 of the motor.

The motor may be any conventional device which, when operated, causes its output drive shaft to rotate about the longitudinal axis 28 of the catheter. Thus, when the motor is operated and its drive shaft 44 rotating, such rotation is transmitted by the coupling 76 and the drive cable 46 to the working head 24.

In order to support the coupling at a centered position within the catheter, i.e., axially aligned with central longitudinal axis 28, the circular peripheral portion 78 of the coupling 76 is located within a central bore 42A of the heretofore identified bushing 42.

An O-ring 82 extends about the periphery of the coupling portion 78 immediately adjacent the distal end of the bushing 42. The O-ring 82 is retained in position within the passageway section 38B by means of a cup-shaped retaining cap 84. The cap 84 is snugly fit within the passageway section 38A. The retaining cap 84 includes a central opening 85 through which the coupling 76 extends. The O-ring 82 serves as a seal to prevent the egress of the water introduced into the interior passageway 38C of the catheter from flowing proximally into passageway section 38A and towards the motor.

The water for lubricating the drive system is introduced via a port 88 in the housing section 26 contiguous with passageway section 38C. A flexible conduit or pipe 90 is connected to the port 88 to carry the water from an electrically insulated source (not shown). The water enters into the catheter 20 via the conduit 90 and associated port 88 and flows through the catheter in the direction of arrows 92 in Figs. 2 and 3. Thus, as can be seen therein, the water flows down the passageway section 38C through the hollow interior of the catheter jacket 22 into the radial slots or inlets 58 and the communicating grooves 56 down the length of

to the shank, the shank includes a retaining flange 96 at its distal end. The flange has a peripheral groove 98 arranged to receive a correspondingly shaped annular projection in the cap 96.

An electrically conductive material, e.g., stainless steel, strip 100 is mounted within the cap 94 so that a portion of the outer surface of the strip is flush with the convex outer surface of the cap. That portion of the strip is oriented so that it extends almost 90° from a location immediately adjacent the central axis 28 at the top of the crown backward to a point close to the rear face of the crown. The strip 100 also includes a portion 102 extending radially inward from the outer surface of the cap into a diametric slot 104 located in the retaining flange 96 of the shank of the working head so that the strip is electrically connected to the working head shank, and from there to the drive cable 46.

The generator for supplying the electrosurgical energy is denoted by reference numeral 30A in Fig. 1 and can be of any suitable construction to provide any type of electrical signal, as desired. In the exemplary embodiment shown herein, the generator 30A includes a positive or "hot" terminal connected, via a cable 30B, to a brush assembly 110. The brush assembly will be described later. Suffice it for now to state that the brush assembly is arranged to carry the electrical energy from cable 30B to the coupling 76 and from there via the drive cable 46 to the working head, and in particular its conductive strip 100. The other terminal of the electrosurge generator 30A is connected, via a cable 30C, to a conventional plate electrode 112. The plate electrode 112 is an electrically conductive member having a large surface area which is arranged to be held in contact with the skin of the patient to complete the electrosurgical circuit.

Referring now to Fig. 3, the details of the brush assembly 110 will be described. As can be seen, the brush assembly 110 basically comprises an electrically conductive externally threaded plug 112. The plug extends into a

shank to the bottom of the bore in which the distal end of the drive cable 46 is located. At that point the section 122 of the electrically conductive strip 100 is electrically connected, e.g., welded, to the drive cable 46.

It should pointed out at this juncture that the two working heads described heretofore are merely exemplary. Thus, other constructions for the working head are contemplated within the scope of this invention.

Without further elaboration, the forgoing will so fully illustrate my invention that others may, by applying current or future knowledge, readily adopt the same for use under various conditions of service.



17. The method of Claim 14 characterized in that said biological material is located within the body of said being, and wherein said method comprises introducing said working head within the body of said being through an opening in the body of said being.

18. The method of Claim 17 characterized in that said opening is formed by a percutaneous incision or puncture.

19. The method of Claim 17 characterized in that said opening is a natural body opening or orifice.

20. The method of Claim 14 characterized in that said material is selected from the group comprising the prostate, liver, and kidney of the being.

21. The method of Claim 15 characterized in that said electrosurge energy is provided to said working head as said working head repeatedly impacts said material.

22. The method of Claim 14 characterized in that the movement of said working head through said path constitutes rotation about said axis.

23. The method of Claim 22 characterized in that said rotation constitutes multiple complete revolutions about said axis, with all of said revolutions being in a single rotational direction.

6. The apparatus of Claim 1 characterized in that said elongated member comprises a tubular portion formed of an electrically insulating material, and a body portion formed of an electrically insulating material.

7. The apparatus of Claim 4 characterized in that said drive means comprises a rotatable drive cable connected to said working head, said drive cable comprising an electrically conductive material and being electrically connected to said electrosurgical generator means.

8. The apparatus of Claim 7 characterized in that said working head includes at least one electrically conductive portion in electrical continuity with said drive cable, and wherein said instrument additionally comprises brush means coupled to said electrosurgical generator means and engaging a portion of said drive cable as said drive cable means is rotated.

9. The apparatus of Claim 8 characterized in that said electrosurgical generator means comprises two electrodes, one of said electrodes being electrically connected to said brush means, the other of said electrodes being electrically connected to an electrically conductive member arranged to be placed in contact with said being.

10. The apparatus of Claim 5 characterized in that said drive means comprises a rotatable drive cable connected to said working head, said drive cable comprising an electrically conductive material and being electrically connected to said electrosurgical generator means.

11. The apparatus of Claim 10 characterized in that said working head includes at least one electrically conductive portion in electrical continuity with said drive cable, and wherein said instrument additionally comprises brush means coupled to said electrosurgical generator means and engaging a portion of said drive cable as said drive cable means is rotated.

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (if several classification symbols apply, indicate all) <sup>10</sup>		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int.Cl. 5 A61B17/32		
<b>II. FIELDS SEARCHED</b>		
Minimum Documentation Searched <sup>7</sup>		
Classification System	Classification Symbols	
Int.Cl. 5	A61B	
Documentation Searched other than Minimum Documentation to the extent that such Documents are included in the Fields Searched <sup>8</sup>		
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT<sup>9</sup></b>		
Category <sup>11</sup>	Citation of Document, <sup>11</sup> with indication, where appropriate, of the relevant passages <sup>12</sup>	Relevant to Claim No. <sup>13</sup>
X	FR,A,2 645 008 (TECHNOMED) 5 October 1990 see page 6, paragraph 2; figure 1 ---	1-13
X	DE,A,2 164 893 (KUTSCHER) 5 July 1973 see page 3, line 1; figure 1 ---	1-13
X	DE,A,3 313 325 (KORTH) 18 October 1984 see page 8, paragraph 1 ---	1,3,4
X	EP,A,0 448 857 (HUANG) 2 October 1991 see figure 2 ---	1
X	GB,A,2 161 081 (KHARKHOV INSTITUTE) 8 January 1986 see figure 1 ---	1
-/-		
<sup>10</sup> Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "I" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
<b>IV. CERTIFICATION</b>		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
21 JUNE 1993	J 6. 07. 93	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE	BARTON S.	

FIG. 2

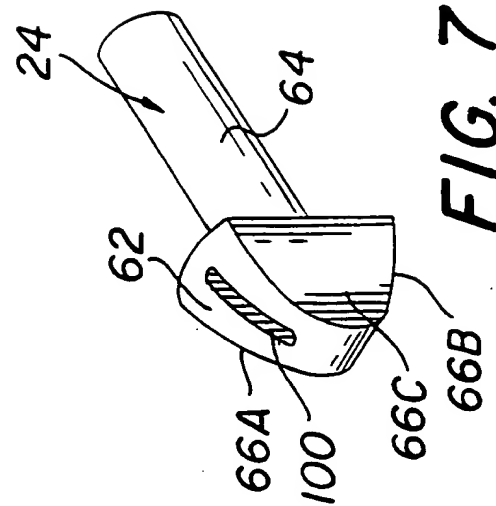
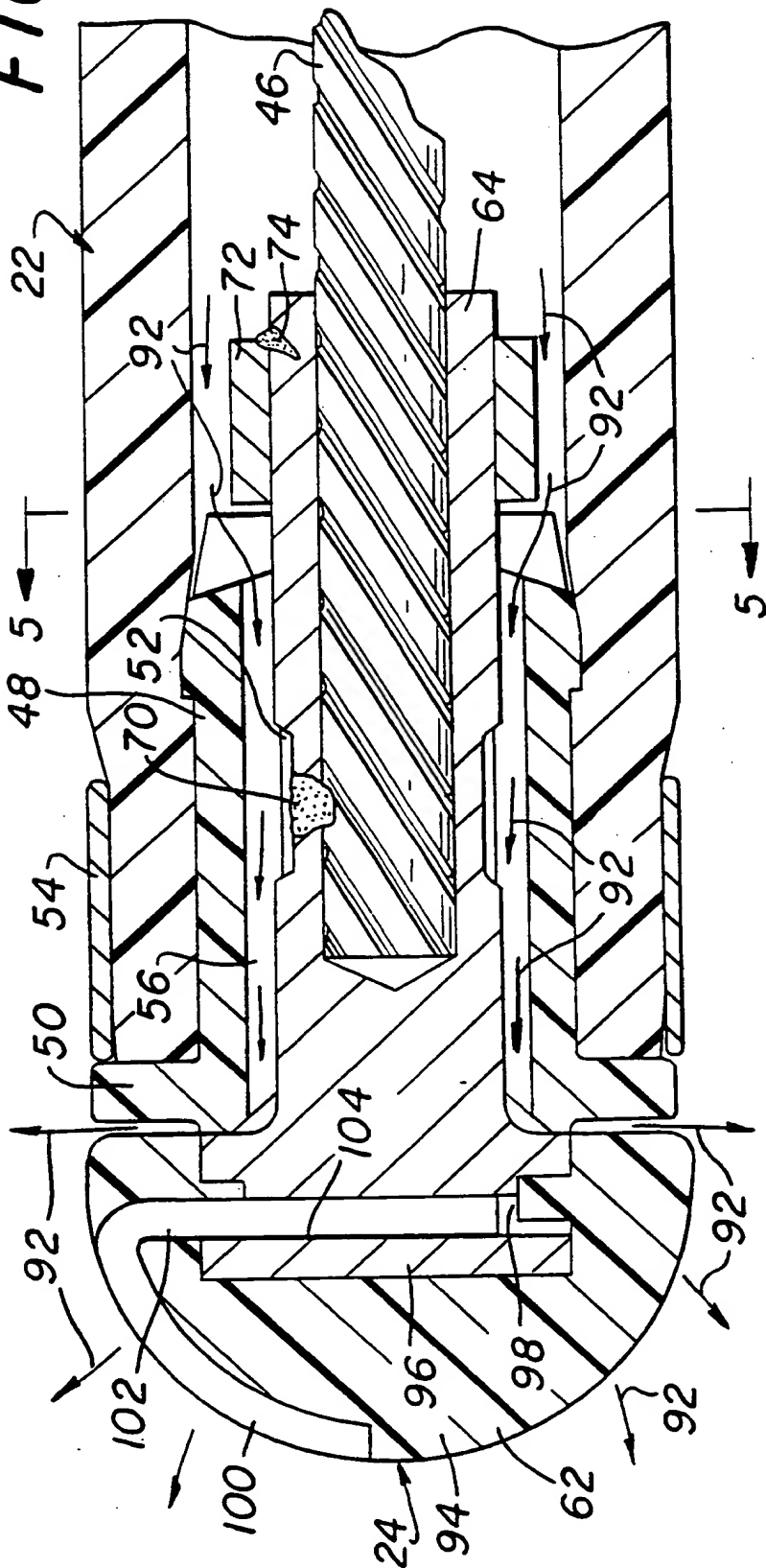


FIG. 7

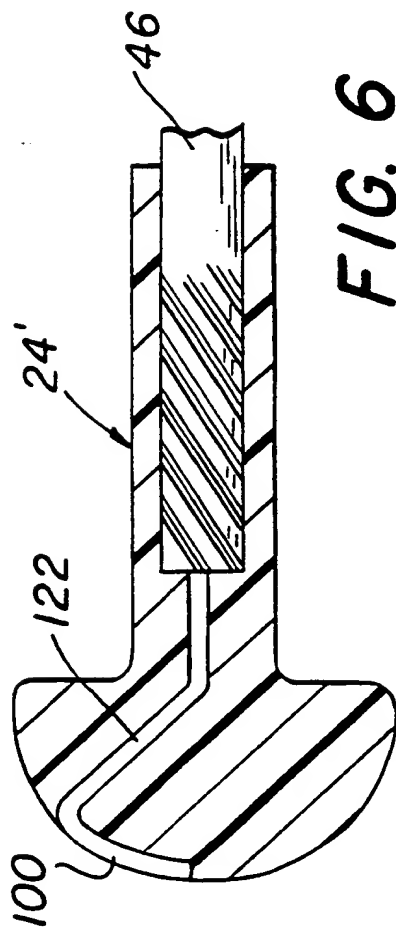


FIG. 6

**ANNEX TO THE INTERNATIONAL SEARCH REPORT  
ON INTERNATIONAL PATENT APPLICATION NO.**

US 9301264  
SA 70124

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.  
The members are as contained in the European Patent Office FDP file on  
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR-A-2645008	05-10-90	None	
DE-A-2164893	05-07-73	None	
DE-A-3313325	18-10-84	JP-A- 60034436	22-02-85
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		US-A- 4747821	31-05-88
		AU-A- 6843687	21-04-88
		EP-A- 0335861	11-10-89
		JP-T- 2500568	01-03-90

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